

## REMARKS

Claims 60, 61, 64-68, and 70-72 are currently pending.

Claims 60 and 61 are amended to clarify the language of the claims. Paragraphing is added to visually separate three elements comprising the claimed material. Support for the term “**material**”, is found within the specification at [0054, 0065, 0066]. Support for the recitation of a “**woven or nonwoven, solid, or flexible mass**” is found within the specification at [0070]. Support for the recitation that the polyionic polymer is “**inherently antimicrobial**” is found at [0053, 0054, 0055, 0057, 0072].

Claim 64 is amended to properly depend from claim 60. Claims 68 and 72 are amended to properly refer to the “**material**” recited in amended claims 60 and 61, respectively.

Applicants note that the Examiner has withdrawn the finality of the previous office action in accordance with the request for continued examination.

The Examiner, in an Office Action mailed on March 6, 2008, rejected all pending claims in the application.

- A. Claims 64 and 65 were rejected under 35 U.S.C. § 112 (2nd paragraph) as being indefinite because they depended from a canceled claim.
- B. Claim 61 was rejected under 35 U.S.C. § 102(b) as being anticipated by Ward et al. U.S. 5,575,993 (“Ward”).
- C. Claim 61 was rejected under 35 U.S.C. § 102(b) as being anticipated by Marlin et al. U.S. 5,645,827 (“Marlin”).
- D. Claim 60 was rejected under 35 U.S.C. § 102(b) as being anticipated by Schoenfeldt et al. U.S. 2002/0172708 (“Schoenfeldt”).
- E. Claims 61 and 70-72 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Batich et al. U.S. 2002/0177828 (“Batich”) in view of Ward or, alternatively, Marlin.
- F. Claims 60 and 64-68 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Batich in view of Schoenfeldt and further in view of Voorhees et al. U.S. 2004/0235950 (“Voorhees”).

Applicants respectfully traverse the Examiner’s rejections of claims 60, 61, 64-68, and 70-72 and request reconsideration and withdrawal of the rejections based on the claim amendments given above and the following remarks.

**A. REJECTION OF CLAIMS 64 and 65 UNDER 35 U.S.C. § 112(2nd) AS BEING INDEFINITE.**

Claim 64 has been amended to properly depend from claim 60. Claim 65 remains dependent from claim 64, now in proper form,

Applicants respectfully request the Examiner to withdraw the rejection of claims 64 and 65 as indefinite and allow the claims.

**B. REJECTION OF CLAIM 61 UNDER 35 U.S.C. § 102(b) AS BEING ANTICIPATED BY WARD.**

Applicants respectfully traverse the rejection. Ward discloses and exemplifies solutions of polyquat-containing compositions and their use as microbicides, disinfectants, sanitizers, etc. [col 1, ln 6-16, Examples 1-30]. Ward discloses applications of polyquat solutions to gauze in a bandage to prevent opportunistic cutaneous infections [col 14, ln 64-66]. Ward further discloses that the polymers can be washed out using normal washing procedures [col 15, ln 2-4]. Ward discloses that the surface affinity of the polyquat polymers allows the polymer to adhere directly to surfaces for direct delivery, timed-release, or sustained-release applications [col 15, ln 12-42].

Applicants' method includes a step to bind the polyquat polymer to a substrate and the resulting polyquat polymer-substrate material is then used for the purpose recited. Ward does not disclose a method for bonding the polyquat to a substrate and using the substrate-bonded polyquats to achieve extended release of an antibiotic, analgesic, or anti-inflammatory as recited in Applicants' claim.

Applicants' claim 61 recites "a woven or nonwoven, solid, or flexible mass" [see also the specification at 0070]. Ward does not disclose any process wherein bonding with such a substrate would take place. Ward exemplifies [Examples 1-30] that the polymer solution is used "as is" after preparation.

Because Ward does not disclose all of the elements of claim 61 as currently amended, Applicants respectfully request the Examiner to withdraw the anticipation rejection of claim 61 and allow the claim.

**C. REJECTION OF CLAIM 61 UNDER 35 U.S.C. § 102(b) AS BEING ANTICIPATED BY MARLIN.**

Applicants respectfully traverse the rejection. Marlin discloses delivery systems for mucosal tissues comprising a clear aqueous solution comprising polysaccharide and an anionic therapeutic agent [col 1, ln 37-43]. Preferred cationic polysaccharides are water-soluble polymers [col 2, ln 64]. They are disclosed as having pendant ammonium groups [col 3, ln 31-67]. The resulting solution of the polysaccharides "is particulate-free and does not form a precipitate, coacervate or is

opalescent" [sic][col 6, ln 26-28].

Applicants' method includes a step to bind the polyquat polymer to a **substrate**, and the resulting polyquat polymer-substrate material is then used for the purpose recited. Marlin does not disclose a method for bonding the polysaccharide to a substrate and using the substrate-bonded compositions to achieve extended release of an antibiotic, analgesic, or anti-inflammatory as recited by Applicants in claim 61.

Applicants' claim 61 recites "a woven or nonwoven, solid, or flexible mass" [see also the specification at 0070]. Marlin does not disclose any process wherein bonding with such a substrate takes place. In fact, Marlin's disclosure of the use of the polysaccharides to treat dry eyes would teach away from bonding the polysaccharides to an opaque and/or insoluble substrate, because then it wouldn't be suitable for use on the surface of the human eye.

Because Marlin does not disclose all of the elements of claim 61 as currently amended, Applicants respectfully request the Examiner to withdraw the anticipation rejection of claim 61 and allow the claim.

**D. REJECTION OF CLAIM 60 UNDER 35 U.S.C. § 102(b) AS BEING ANTICIPATED BY SCHOENFELDT.**

Applicants respectfully traverse the rejection. Schoenfeldt discloses a sol-gel comprising one or more hydrophilic (cationic and/or anionic) polymers and pharmaceutical medicaments. Cationic groups, such as primary, secondary, or tertiary alkyl, cycloalkyl, or aromatic amines, may be linked to the cationic polymer backbone [0041]. Anionic groups attached to anionic polymers include sulfates and acids. The preferred polymer backbone is a polysaccharide or a derivative thereof [0044].

Schoenfeldt discloses a process wherein the hydrophilic or polyionic polymers are crosslinked via covalent or ionic bonds are dissolved or solubilized in a liquid phase comprising pure water or an aqueous solution to provide a sol gel. The gel is kept below freezing and selectively dehydrated to provide a non-fibrous, porous material. The material may be subjected to a dry heat treatment [0020, 0061]. The resulting non-fibrous material may be swellable but not soluble in water [0056].

Schoenfeldt does not disclose a process wherein quaternary ammonium polymers or copolymers are polyionic polymers as recited in Applicants' claim 60. Schoenfeldt also does not disclose a process wherein quaternary ammonium polymer is bound to a woven or nonwoven, solid, or flexible mass as recited by Applicants. Furthermore, Schoenfeldt does not disclose polymers wherein the cationic polymer backbone is comprised of quaternary ammonium groups. Schoenfeldt teaches away from the use of quaternary ammonium groups by teaching that primary amine groups preferably be attached to the cationic polymer backbone [0042].

Applicants assert that Schoenfeldt does not disclose each and every element of claim 60 and therefore, can not anticipate the claim. Applicants respectfully request the Examiner to withdraw the anticipation rejection of claim 60 and allow the claim.

**E. REJECTION OF CLAIMS 61 and 70-72 UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER BATICH IN VIEW OF WARD OR MARLIN.**

Applicants respectfully traverse the rejection and argue that Batich, in view of Ward or Marlin, does not make claims 61 and 70-72 obvious to one of ordinary skill in the art.

Applicants incorporate by reference and reassert their arguments, with respect to Batich, presented in the November 6, 2006 and June 22, 2007 Responses. In summary, Batich does not teach or suggest an anionic agent, such as an antibiotic, analgesic, anti-inflammatory, or a combination thereof, which is ionically associated with a quaternary ammonium polymer or copolymer to achieve extended release of said anionic agent as recited in claim 61. Batich does disclose that the cationic antimicrobial groups, the quaternary ammonium groups, may be intentionally made to be more susceptible to release [0057]. However, there is no disclosure or suggestion that anionic antibiotic, analgesic, or anti-inflammatory substances are associated with the cationic groups and could be made susceptible to release. Furthermore, there is no disclosure or suggestion in Batich that these anionic substances would have extended release characteristics.

Lastly, Batich discloses and exemplifies that the bonds of the quaternary ammonium polymer or co-polymer are non-hydrolyzable and are stable when exposed to body fluids and other aqueous environments [0055]. The polymers readily absorb aqueous solutions [0058] and, when bound to the substrate, are not rinsed off with aqueous rinsings [Example 1].

Ward discloses solutions of ionene polymers comprising polyquaternary ammonium compounds having anionic biologically-active compounds associated with the compounds. Ward discloses that the solutions of ionene polymers may be applied to gauze. However, the ionene polymers are not bound to the gauze and can be readily washed out during normal washings [col 15, ln 2-4]. Ward does not disclose or suggest that polyquaternary ammonium compounds are bound to a substrate and nor does Ward discloses or suggest that the anionic biologically active compounds associated with the polyquaternary ammonium compounds are capable of having extended release characteristics.

One with ordinary skill in the art would not look to Ward as a source for the concept of extended release anions because Ward does not suggest that type of activity. Ward does not suggest that the ionene polymers could be bound to a woven or nonwoven, solid, or flexible substrate such as gauze. In fact, Ward clearly discloses that that the polymers, and therefore the associated anions, are readily

washed out of the gauze. Furthermore, one of ordinary skill in the art would not look to Ward's water-soluble polymers with associated anions as a source for non-hydrolyzable polymers containing therapeutic agents.

Marlin discloses delivery systems comprising a clear aqueous solution of a cationic polymer and an anionic therapeutic agent [col 1, ln 37-43]. Marlin's invention is directed toward treatments on the surface of the eye and inside linings of the mouth, nose, and vagina [col 2, lin 6-18]. The aqueous solutions are administered via drops, gels, lotions, or creams [col 6, ln 44-47].

The solutions of Marlin are not disclosed nor suggested as being capable of binding the polymer or anionic therapeutic agent to woven or nonwoven, solid, or flexible substrate to achieve extended release. Because the solutions are not used with such a substrate, there is no suggestion or reason for one of ordinary skill in the art to conceive that the cationic polymers be non-hydrolyzably bound to such substrates. Neither does Marlin provide any suggestion or reason to conceive that anion therapeutic agents associated with the cationic polymers would have extended release properties relative to such substrates.

The Examiner concedes that Batich does not specifically disclose the use of metalloproteinase inhibitors, such as GM 1489. Batich does not disclose or suggest using anionic therapeutic agents in combination with the compositions. Neither does Batich provide any reason to incorporate anionic therapeutic agents.

Applicants assert that the combination of Batich with either Ward or Marlin does not make obvious to one of ordinary skill in the art the invention as claimed in claims 61 and 70-72 of the instant application. Batich does not suggest combining anionic therapeutic agents with quaternary ammonium polymers to achieve extended release characteristics. Neither does Ward or Marlin supply what is missing from the disclosure of Batich as discussed above with regard to claim 61.

Applicants respectfully request the Examiner to withdraw the obviousness rejection of claims 61 and 70-72 and allow the claims as currently amended.

**F. REJECTION OF CLAIMS 60 and 64-68 UNDER 35 U.S.C. § 103(a) AS BEING UNPATENTABLE OVER BATICH IN VIEW OF SCHOENFELDT AND VOORHEES.**

Applicants respectfully traverse the rejection and submit that Batich, in view of Schoenfeldt and Voorhees, does not make claims 60 and 64-68 obvious to one of ordinary skill in the art.

Applicants incorporate by reference and reassert their arguments concerning Batich, Schoenfeldt, and Voorhees presented in the November 6, 2006 and June 22, 2007 Responses. In summary, Batich does not teach or suggest a matrix metalloproteinase inhibitor, which is ionically associated with a quaternary ammonium polymer or copolymer to achieve extended release of said matrix

metalloproteinase inhibitor as recited in claim 60.

Batich does disclose that the cationic antimicrobial groups, the quaternary ammonium groups, may be intentionally made to be more susceptible to release [0057]. However, there is no disclosure or suggestion that **anionic** antibiotic, analgesic, or anti-inflammatory substances are associated with the cationic groups and could likewise being made more susceptible to release. Furthermore, there is no disclosure or suggestion in Batich that matrix metalloproteinase inhibitors would have extended release characteristics.

Lastly, Batich discloses and exemplifies that the bonds of the quaternary ammonium polymer or co-polymer are non-hydrolyzable and are stable when exposed to body fluids and other aqueous environments [0055]. The polymers readily absorb aqueous solutions [0058] and, when bound to the substrate, are not rinsed off with aqueous rinsings [Example 1].

As discussed above, Schoenfeldt discloses a method of preparing a sol gel comprising crosslinked polyionic polymers and pharmaceutical medicaments. The sol gel is dehydrated to provide a non-fibrous porous material which may be used as a preparation for a dressing or an absorbent article [0016]. The material is swellable but is not soluble in water [0056].

Schoenfeldt does not suggest a process wherein quaternary ammonium polymers or copolymers are components of polyionic polymers as recited in Applicants' claim 60. Schoenfeldt also does not suggest a process the sol gel is bound to a substrate. Schoenfeldt discloses that the dehydrated sol gel may be a product in itself or be a component of a product [0060]. However, there is no suggestion that the dehydrated and non-fibrous sol gel material is bound to a substrate that is a woven or nonwoven, solid, or flexible mass. Furthermore, Schoenfeldt does not suggest polymers wherein the cationic polymer backbone is comprised of quaternary ammonium groups. Schoenfeldt teaches away from the use of quaternary ammonium groups by preferring that primary amine groups be attached to the cationic polymer backbone [0042].

Voorhees discloses treatments for acne by topical, systemic (preferably oral), or a combination thereof applications of compositions comprising an effective amount of a non-retinoid or non-glucocorticoid inhibitor [0010]. The inhibitor may be a combination of an MMP inhibitor and an elastase inhibitor [claim 17]. Voorhees includes a long list of references to possible elastase inhibitors including trialkylammonium salts and alkyltrimethylammonium salts. [0044].

Voorhees does not disclose or suggest the use of **polymeric** ammonium salts. Voorhees does not disclose or suggest that the ammonium salts have any effect on the release of the other components of the mixture, including the MMP inhibitors, when applied to the skin or taken orally. Voorhees does not disclose or suggest that the compositions are non-hydrolyzably bound to a substrate nor are the compositions discloses or suggested to be absorbent materials.

Batich alone does not anticipate or make obvious to one of ordinary skill in the art Applicants' invention as claimed. One of ordinary skill in the art would not look to Schoenfeldt and Voorhees to supply what is missing from the disclosure of Batich with regard to claim 61. Schoenfeldt teaches away from the use of quaternary ammonium compounds. Voorhees does not disclose methods of binding the ammonium salts to a substrate nor methods of using the compositions in conjunction with an insoluble substrate. Neither Schoenfeldt nor Voorhees suggest the binding their compositions to a substrate that is a woven or nonwoven, solid, or flexible mass in order to obtain extended release of bioactive components as disclosed by Applicants.

Therefore, Applicants assert that the combination of Batich, Schoenfeldt, and Voorhees does not make obvious the invention as disclosed. Applicants respectfully request the Examiner to withdraw the obviousness rejection of claims 60 and 64-68 and allow the claims as currently amended.

## CONCLUSION

Applicants respectfully traverse all of the rejections. Claim 64 has been amended to correct dependency. Claims 60 and 61 are not anticipated because the prior art does not disclose each and every element of the claims. Claims 60 and 64-68 are not made obvious to one of ordinary skill in the art by the disclosures of Batich, Schoenfeldt, and Voorhees as described above. Claims 61 and 70-72 are not made obvious to one of ordinary skill in the art by the disclosures of Batich, Ward, or Marlin as described above.

Applicants respectfully request the Examiner to withdraw the rejections for the reasons explained above and allow claims 60, 61, 64-68, and 70-72 as currently amended.

Respectfully submitted:

June 3, 2008

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